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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
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| 09/737,542   | 12/14/2000  | Robin R. Miles       | IL-10406                | 9714             |
| 7590 12/02/2003  |             |                      | EXAMINER                |                  |
| Alan H. Thompson Assistant Laboratory Counsel Lawrence Livermore National Laboratory |             |                      | PADMANABHAN, KARTIC     |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
| P.O. Box 808, L-703  |             |                      | 1641                    | 20               |
| Livermore, CA 94551  |             |                      | DATE MAILED: 12/02/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.                    | Applicant(s)                                       |  |  |  |  |
|---|------------------------------------|--|--|--|--|--|
|   | 09/737,542                         | MILES ET AL.                                       |  |  |  |  |
| Office Action Summary   | Examiner                           | Art Unit   |  |  |  |  |
|   | Kartic Padmanabhan                 | 1641   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                                    |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status                   |                                    |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 11 Se  | eptember 2003.                     |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ☑ This a  | action is non-final.               |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                                    |  |  |  |  |  |
| Disposition of Claims   |                                    |  |  |  |  |  |
| 4)⊠ Claim(s) <u>10-28</u> is/are pending in the application.  |                                    |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                                    |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                                    |  |  |  |  |  |
| 7) Claim(s) <u>10-28</u> is/are rejected. 7) Claim(s) is/are objected to.   | 6) Claim(s) 10-28 is/are rejected. |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.              |  |  |  |  |  |
| Application Papers  |                                    |  |  |  |  |  |
| 9) The specification is objected to by the Examine  | г.                                 |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce   | epted or b) objected to by the I   | Examiner.  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                                    |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |                                    |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. §§ 119 and 120   |                                    |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                                    |  |  |  |  |  |
| <ul> <li>a) All b) Some * c) None of: <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> </li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78. <ul> <li>a) The translation of the foreign language provisional application has been received.</li> </ul> </li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific</li> </ul> |                                    |  |  |  |  |  |
| reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.   |                                    |  |  |  |  |  |
| Attachment(s)   |                                    |  |  |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>  | 5) Notice of Informal P            | (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |

Art Unit: 1641

#### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/03 has been entered.

# Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 15, 22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 15 is rejected as vague and indefinite for the recitation of "said means" because the parent claim (claim 10) recites multiple means that refer to different elements, rendering it unclear to which means applicant is referring in claim 15.
- 5. Claim 22 is rejected as vague and indefinite because it depends from claim 1, whish is no longer pending.
- 6. Claim 25 is rejected as vague and indefinite for the recitation of "said surface" because the parent claim (claim 24) recites multiple surfaces (of the electrodes and the channel), rendering it unclear to which surface applicant is referring in claim 25.

Art Unit: 1641

## Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. Claims 10, 12-18, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gerwen et al. (WO 97/21094).

Van Gerwen et al. teach an impedimetric detection system comprising an insulating layer with a plurality of interspersed channels therein. A metal coating is applied to one of the two

Art Unit: 1641

Page 4

opposite side walls of each channel and on top of the dielectric layer in between said channels, thereby forming an impedimetric device. Probes are applied to either the insulating part of the channels or to the surface of the electrodes or both (abstract). The device also comprises means for applying a voltage on the metal coatings and measuring the impedance between the electrodes. The sensor of the reference also has an interdigitated electrode structure (page 10, lines 10-16 and page 15, line 28). The probes of the device include antibodies (page 5 and figures 1-7). When an electric signal is applied (voltage or current), an electric field arises. If the analyte is present in the solution tested, it will be bound to the probe on the electrode surface, resulting in a change in impedance, which is then quantified (page 15). It is inherent that the means for producing the electric field is an AC or DC power supply. However, the reference does not teach pairs of electrodes located on the same surface and/or same side of the microchannel or on a bottom surface of the channel.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to place the electrode pair on the same side of the microchannel, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. In addition, the placement of the electrodes on a bottom surface of the microchannel would have been obvious because it simply represents an optimization of the device or a rearrangement of the parts of the device, which one would have had a reasonable expectation of success in using.

11. Claims 10, 12-13, 16, and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,194,133) in view of Kipling et al. (US Pat. 5,374,521).

Clark et al. teach sensor devices comprising pairs of sensing electrodes that are spaced

Art Unit: 1641

apart along the walls of a channel that has been micromachined in a surface of a substrate (abstract). The channel walls may be coated with a biological substance, such as an enzyme (col. 1). The electrodes may be amperometric enzyme electrodes (Col. 3, lines 48-50). The sensors of the reference may be used to measure impedance between electrodes (col. 5, lines 50-55). A DC pulse may be used generate the electric field (col. 5, lines 60-65). The reference also teaches a plurality of signal generators and a plurality of amplifier/mixer assemblies (Figure 6). The reference does not teach antibodies located on the electrodes.

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Clark et al. because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would have known that a number of receptors could have been placed on the electrodes of Clark et al. with a reasonable expectation of success. In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to place the electrode pair

Page 6

Application/Control Number: 09/737,542

Art Unit: 1641

on the same side of the microchannel, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Also, the placement of the electrodes on a bottom surface of the microchannel would have been obvious because it simply represents an optimization of the device or a rearrangement of the parts of the device, which one would have had a reasonable expectation of success in using.

12. Claims 11, 14, 17-19, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,194,133) in view of Kipling et al. (US Pat. 5,374,521) as applied to claims 10, 12-13, 16, and 20-21 above, and further in view of Taylor et al. (US Pat. 5,001,048).

Clark et al. and Kipling et al. teach sensor devices, as discussed above. However, the references do not teach the use of reference electrodes or an interdigitated electrode assembly.

Taylor et al. teach an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the

Art Unit: 1641

reference and receptor-containing electrode to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the reference electrodes and insulating layer, as well as the interdigitated electrode assembly of Taylor et al. with the modified sensor of Clark et al. and Kipling et al. One would have been motivated to use a reference electrode in an insulating layer to determine a background signal, wherein a difference from background can be used as an indication of the analyte of interest. Further, an insulator provides the advantage of preventing current flow between the reference electrode and sensor electrode, which results in a contamination of assay results. It would have also been obvious to use an interdigitated electrode assembly because Clark et al. state that a number of electrode configurations can be used with the device of their reference. Further, the configuration depicted in figure 4 of the reference resembles an interdigitated assembly, and one would expect such a configuration to work with their sensor.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,194,133) in view of Kipling et al. (US Pat. 5,374,521) as applied to claims 10, 12-13, 16, and 20-21 above, and further in view of Stetter et al. (US Pat. 5,567,301).

Clark et al. and Kipling et al. teach sensor devices, as discussed above. However, the references do not teach the use of an AC source.

Stetter et al. teach a biosensor comprising two spaced metal electrodes, wherein at least one antibody is disposed on and/or between the two electrodes. The sensor also comprises impedance detection means for measuring the impedance between the two electrodes (cols. 3-4).

Art Unit: 1641

Since figure 2 shows the impedance as a function of the AC frequency, the presence of an AC power source for the production of an electric field across the electrodes is inherent.

It would have been *prima facie* obvious to use the AC power source of Stetter et al. with the sensor of Clark et al. and Kipling et al. because the use of AC impedance is very well known in the art, and one would have known that an AC source could have easily been substituted for the DC source of Clark et al. with a reasonable expectation of success.

14. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Gerwen et al. (WO 97/21094) as applied to claims 10, 12-18, and 21-28 above, and further in view of Taylor et al. (US Pat. 5,374,521).

Van Gerwen et al. teach a sensor device, as previously discussed. However, the reference does not teach reference electrodes or insulation.

Taylor et al. teach an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the

Art Unit: 1641

reference and receptor-containing electrode to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the reference electrodes and insulating layer of Taylor et al. with the sensor of van Gerwen et al. because the use of a reference electrode in an insulating layer allows the determination of a background signal, wherein a difference from background can be used as an indication of the analyte of interest. Further, an insulator provides the advantage of preventing current flow between the reference electrode and sensor electrode, which results in a contamination of assay results.

15. Claims 10-28 are rejected under 35 U.S.C. 103(a) as being obvious over Miles (US 2002/0070114 A1) in view of Kipling et al. (US Pat. 5,374,521).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this

Art Unit: 1641

rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Miles teaches a device for detecting the presence of pathogens trapped in an electric field, comprising a fluidic channel, at least one pair of interdigitated electrodes positioned in the surface of the channel, an AC power source for applying a voltage across the electrodes, and means for measuring the impedance between electrodes as an indication of pathogen presence.

The device also comprises a plurality of signal generators, amplifiers and mixers. However, the reference does not teach antibodies immobilized on the electrodes (See claims).

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Miles because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would

Art Unit: 1641

have known that a number of receptors could have been placed on the electrodes of Miles with a reasonable expectation of success.

16. Claims 10-28 are rejected under 35 U.S.C. 103(a) as being obvious over Krulevitch et al. (US Pat. 6,437,551 B1) in view of Kipling et al. US Pat. 5,374,521).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Krulevitch et al. teach a device comprising at least one fluidic channel, at least one pair of spaced electrodes positioned in the surface of the channel, an AC power source for applying a voltage across the electrodes, and means for measuring the impedance between electrodes. The

Art Unit: 1641

device also comprises reference electrodes. However, the reference does not teach antibodies immobilized on the electrodes.

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Krulevitch et al. because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would have known that a number of receptors could have been placed on the electrodes of Krulevitch et al. with a reasonable expectation of success.

### Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1641

F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 10-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-21 of copending Application No. 09/993,870 (US 2002/0150886 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite devices for determining the trapping of pathogens by antibodies deposited in a fluidic channel comprising a fluidic channel having at least one pair of spaced electrodes, antibodies located on the spaced electrodes, means for producing an electric field across the spaced electrodes, and an impedance sensor for measuring the impedance between the electrodes, and one of ordinary skill in the art would recognize that the two sets of claims read on one another and are thus not patentably distinct.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Page 14

Application/Control Number: 09/737,542

Art Unit: 1641

19. Claims 10-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/738,927 (US 2002/0070114 A1) in view of Kipling et al. (US Pat. 5,374,521).

Miles teaches a device for detecting the presence of pathogens trapped in an electric field, comprising a fluidic channel, at least one pair of interdigitated electrodes positioned in the surface of the channel, an AC power source for applying a voltage across the electrodes, and means for measuring the impedance between electrodes as an indication of pathogen presence.

The device also comprises a plurality of signal generators, amplifiers and mixers. However, the reference does not teach antibodies immobilized on the electrodes (See claims).

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Miles because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would

Art Unit: 1641

have known that a number of receptors could have been placed on the electrodes of Miles with a reasonable expectation of success.

This is a <u>provisional</u> obviousness-type double patenting rejection.

20. Claims 10-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,437,551 B1 in view of Kipling et al. US Pat. 5,374,521).

Krulevitch et al. teach a device comprising at least one fluidic channel, at least one pair of spaced electrodes positioned in the surface of the channel, an AC power source for applying a voltage across the electrodes, and means for measuring the impedance between electrodes. The device also comprises reference electrodes. However, the reference does not teach antibodies immobilized on the electrodes.

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Krulevitch et al. because Kipling teaches that any number of biomolecules can

Art Unit: 1641

be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would have known that a number of receptors could have been placed on the electrodes of Krulevitch et al. with a reasonable expectation of success.

# Response to Arguments

21. Applicant's arguments filed 9/11/03 have been fully considered but they are not persuasive.

22. Applicant's arguments amount to general conclusions that the features present in the current claims are not present in the prior art without specifically addressing what the prior art teaches and how the claims differ. In essence, applicant's arguments do not clearly point out the patentable novelty that he or she thinks the claims present in view of the state of the art disclosed by the references cited. Further, they do not show how the amendments avoid such references or objections. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references is prima facie unconvincing because it is only a simple conclusion without any basis in fact or law.

### Conclusion

Claims 10-28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

Art Unit: 1641

Page 17

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-5207.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan Patent Examiner Art Unit 1641

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LONG V. LE

SUPERIOR FATENT EXAMINER 1600

11/28/09